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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,088	03/16/2001	Douglas A. Holtzman	MP12000-540OMNI(M)	8287

7590 06/26/2002

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS INC.
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EXAMINER
KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
1646	10

DATE MAILED: 06/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,088	HOLTZMAN ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 12 (each in part) and 26, drawn to nucleic acids encoding SEQ ID NO: 2 and generic fragments and variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptide, classified in class 435, subclass 325, for example.

II. Claims 1-7, 12 (each in part) and 27, drawn to nucleic acids encoding SEQ ID NO: 4 and generic fragments and variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptide, classified in class 435, subclass 325, for example.

III. Claims 1-7, 12 (each in part) and 28, drawn to nucleic acids encoding SEQ ID NO: 6 and generic fragments and variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptide, classified in class 435, subclass 325, for example.

IV. Claims 1-7, 12 (each in part) and 29, drawn to nucleic acids encoding SEQ ID NO: 8 and generic fragments and variants thereof, vectors comprising same, host cells comprising same, and methods of

recombinantly expressing the encoded polypeptide, classified in class 435, subclass 325, for example.

V. Claims 1-7, 12 (each in part) and 30, drawn to nucleic acids encoding SEQ ID NO: 10 and generic fragments and variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptide, classified in class 435, subclass 325, for example.

VI. Claims 8-10 (each in part) and 31, drawn to SEQ ID NO: 2 polypeptides, classified in class 530, subclass 399, for example.

VII. Claims 8-10 (each in part) and 32, drawn to SEQ ID NO: 4 polypeptides, classified in class 530, subclass 399, for example.

VIII. Claims 8-10 (each in part) and 33, drawn to SEQ ID NO: 6 polypeptides, classified in class 530, subclass 399, for example.

IX. Claims 8-10 (each in part) and 34, drawn to SEQ ID NO: 8 polypeptides, classified in class 530, subclass 399, for example.

X. Claims 8-10 (each in part) and 31, drawn to SEQ ID NO: 10 polypeptides, classified in class 530, subclass 399, for example.

XI. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 2 and methods of using and making same, classified in class 530, subclass 387.1, for example.

XII. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 4 and methods of using and making same, classified in class 530, subclass 387.1, for example.

XIII. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 6 and methods of using and making same, classified in class 530, subclass 387.1, for example.

XIV. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 8 and methods of using and making same, classified in class 530, subclass 387.1, for example.

XV. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 10 and methods of using and making same, classified in class 530, subclass 387.1, for example.

XVI. Claims 16 and 17 (each in part), drawn to methods for detecting the presence of a nucleic acid encoding SEQ ID NO: 2, classified in class 435, subclass 6, for example.

XVII. Claims 16 and 17 (each in part), drawn to methods for detecting the presence of a nucleic acid encoding SEQ ID NO: 4, classified in class 435, subclass 6, for example.

XVIII. Claims 16 and 17 (each in part), drawn to methods for detecting the presence of a nucleic acid encoding SEQ ID NO: 6, classified in class 435, subclass 6, for example.

XIX. Claims 16 and 17 (each in part), drawn to methods for detecting the presence of a nucleic acid encoding SEQ ID NO: 8, classified in class 435, subclass 6, for example.

XX. Claims 16 and 17 (each in part), drawn to methods for detecting the presence of a nucleic acid encoding SEQ ID NO: 10, classified in class 435, subclass 6, for example.

XXI. Claim 18 (in part), drawn to a kit comprising a compound that selectively hybridizes with a nucleic acid molecule that encodes SEQ ID NO: 2, classification dependent upon structure of compound.

XXII. Claim 18 (in part), drawn to a kit comprising a compound that selectively hybridizes with a nucleic acid molecule that encodes SEQ ID NO: 4, classification dependent upon structure of compound.

XXIII. Claim 18 (in part), drawn to a kit comprising a compound that selectively hybridizes with a nucleic acid molecule that encodes SEQ ID NO: 6, classification dependent upon structure of compound.

XXIV. Claim 18 (in part), drawn to a kit comprising a compound that selectively hybridizes with a nucleic acid molecule that encodes SEQ ID NO: 8, classification dependent upon structure of compound.

XXV. Claim 18 (in part), drawn to a kit comprising a compound that selectively hybridizes with a nucleic acid molecule that encodes SEQ ID NO: 10, classification dependent upon structure of compound.

XXVI. Claims 19, 20 and 22 (each in part), drawn to methods for identifying compounds that bind or modulate SEQ ID NO: 2, classification dependent upon structure of compound.

XXVII. Claims 19, 20 and 22 (each in part), drawn to methods for identifying compounds that bind or modulate SEQ ID NO: 4, classification dependent upon structure of compound.

XXVIII. Claims 19, 20 and 22 (each in part), drawn to methods for identifying compounds that bind or modulate SEQ ID NO: 6, classification dependent upon structure of compound.

XXIX. Claims 19, 20 and 22 (each in part), drawn to methods for identifying compounds that bind or modulate SEQ ID NO: 8, classification dependent upon structure of compound.

XXX. Claims 19, 20 and 22 (each in part), drawn to methods for identifying compounds that bind or modulate SEQ ID NO: 10, classification dependent upon structure of compound.

XXXI. Claim 21 (in part), drawn to methods for modulating the activity of SEQ ID NO: 2 comprising administering a compound, classification dependent upon structure of compound.

XXXII. Claim 21 (in part), drawn to methods for modulating the activity of SEQ ID NO: 4 comprising administering a compound, classification dependent upon structure of compound.

XXXIII. Claim 21 (in part), drawn to methods for modulating the activity of SEQ ID NO: 6 comprising administering a compound, classification dependent upon structure of compound.

XXXIV. Claim 21 (in part), drawn to methods for modulating the activity of SEQ ID NO: 8 comprising administering a compound, classification dependent upon structure of compound.

XXXV. Claim 21 (in part), drawn to methods for modulating the activity of SEQ ID NO: 10 comprising administering a compound, classification dependent upon structure of compound.

The inventions are distinct, each from the other because of the following reasons:

First, for each grouping of Inventions I-V, VI-X, XI-XV, XVI-XX, XXI-XXV, XXVI-XXX, and XXXI-XXXV, the inventions are independent and distinct because SEQ ID NOS: 2, 4, 6, 8 and 10 are structurally and functionally unrelated. Furthermore, a search for any one of the sequences would not reveal art relevant to the other sequences.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-XV and XXI-XXV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The nucleic acids of Groups I-V

can be used other than to make the proteins of Groups VI-X, such in gene therapy or as a probe in nucleic acid hybridization assays. The proteins of Groups VI-X can be prepared by processes which are materially different from recombinant DNA expression of Groups I-V, such as by chemical synthesis, or by isolation and purification from natural sources. Although the antibodies Groups XI-XV can be used to obtain the nucleic acids of Groups I-V, they can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The proteins of Groups VI-X can be used in materially different methods other than to make the antibodies of Groups XI-XV, such as in therapeutic or diagnostic methods (e.g., in screening). The kits of Groups XXI-XXV are independent and distinct from the nucleic acids of Groups I-V because they are not clearly structurally or functionally related, and would require a non-coextensive search. The kits of Groups XXI-XXV are independent and distinct from the proteins of Groups VI-X because the compounds in the kits o not bind the proteins, and are structurally and functionally distinct. The kits of Groups XXI-XXV are independent and distinct from the antibodies of Groups XI-XV because the compounds in the kits are structurally and functionally independent fro the antibodies, and they do not bind one another.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups XVI-XX, XXVI-XXX and XXXI-XXXV are directed to methods that are distinct both physically and

functionally, and are not required one for the other. Inventions XVI-XX require search and consideration of hybridization analysis, which is not required by the other method claims. Inventions XXVI-XXX require search and consideration of protein-compound interactions, which is not required by any of the other claims. Inventions XXXI-XXXV require search and consideration of protein activity modulation, which is not required by any of the other claims.

Each if the following pairs of Inventions are related as product and process of use: I/XVI; II/XVII; III/XVIII; IV/XIV; and V/XV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Inventions I-V can be used to produce protein recombinantly, or in gene therapy.

Each if the following pairs of Inventions are related as product and process of use: VI/XXVI; VI/XXXI; VII/XXVII; VII/XXXII; VIII/XXVIII; VIII/XXXIII; IX/XXIX; IX/XXXIV; X/XXX; and X/XXXV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Inventions VI-X can be used to raise an antibody, or to purify a receptor.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. Additionally, the method of each remaining pair does not require use of the product of each remaining pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK
June 25, 2002